

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

REMARKS

This Amendment is being filed concurrently with an RCE.

The Final Office Action mailed August 30, 2010, has been carefully reviewed and Applicants note with appreciation the indication of allowable subject matter.

By this Amendment, claims 4 and 28-31 have been canceled, claims 1-3, 5-9, 11, 19, 20, 22 and 24 have been amended, and claims 32-35 has been added. Claims 1-3, 5-27 and 32-35 are pending in the application. Claims 1, 25 and 32 are independent. Claims 25-27 have been withdrawn.

As an initial matter, Applicants have amended the specification in light of amendments made to claim 1. These amendments are supported in the original application by Figures 5, 9, 10, 11a, 11b and 12, and also by claim 4 as filed. No new matter has been added.

The Examiner objected to claims 2 and 24 as containing informalities which have been corrected with the amendments set forth herein. Favorable reconsideration and withdrawal of the objection is requested.

The Examiner rejected claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite. With the amendments to claim 1 set forth herein, claim 1 is in conformity with 35 U.S.C.

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

112, second paragraph. Favorable reconsideration and withdrawal of the rejection is requested.

The Examiner rejected claims 1 and 22 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 7,722,586. The Examiner also rejected claim 1 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 7,470,263. Applicants request that further response in connection with these issues be deferred pending the full identification of allowable subject matter in the present application.

The Examiner rejected claims 1-8, 11-13, 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,785,695 to Sato et al. ("Sato") in view of U.S. Patent No. 4,826,495 to Petersen. Also under 35 U.S.C. 103(a), the Examiner rejected claims 9 and 10 as being unpatentable over Sato in view of U.S. Patent No. 5,520,670 to Blum, rejected claims 14, 15, 18 and 19 as being unpatentable over Sato in view of Petersen and further in view of U.S. Publ. No. 2005/0113770 to Pedersen et al ("Pedersen"), rejected claims 16 and 20 as being unpatentable over Sato in view of Petersen and Pedersen and further in view of U.S. Patent No. 2,660,877 to Malouf, and rejected claims 17 and 21 as being unpatentable over Sato in view of Petersen and

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

Pedersen in view of Malouf and further in view of U.S. Patent No. 2,708,802 to Baker et al. The Examiner objected to claim 22 as being dependent on a rejected base claim but stated that claim 22 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if the obviousness-type double patenting rejection is overcome.

As amended herein, claim 1 is directed to a disposable inner bag liner for an ostomy appliance applied to a human body, the inner bag liner being capable of forming a bag inside an outer receiving member that has a flange and a hole for receiving a stoma, ureter, or catheter through which effluents or waste products of the body are received. The disposable inner bag liner includes an open end having an annular flange that has a hole for receiving a stoma, ureter, or catheter for receiving effluents or waste products of the body, a first surface provided with an adhesive and a release liner, and a second surface. The outer receiving member flange and the second surface of the liner are adapted to be releasably adhered to each other, and the release liner is removed prior to adhering the bag liner first surface to a base plate on a user.

The release liner on the first surface of the flange includes a first alignment element for aligning the inner bag

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

liner flange in relation to the outer receiving member flange, and the outer receiving member flange has a second alignment element adapted to cooperate with the first alignment element of the release liner such that the *inner bag liner flange is retained in a direction substantially parallel with said outer receiving member flange.* This claimed structure, which is supported in the original application by Figures 5, 9, 10, 11a, 11b and 12, as well as by original claim 4, is not shown by the prior art.

Sato teaches fitting portions on two mating flanges (see column 3, line 60 to column 4, line 9). These mating flanges do not correspond with a removable release liner having an alignment element as claimed. Further, Sato does not disclose an alignment element on a release liner that is removed prior to adhering the bag liner first surface to a base plate on the user.

The Examiner states that it would have been obvious to move the alignment element to a release liner since both locations perform the same function of aligning and therefore moving the alignment element would only be a matter of rearranging parts. Applicants do not agree.

In Sato, the alignment elements 6 and 9 are intended to retain the coupling of the inner bag 15 to the outer pouch 10 (see column 7, lines 48-61). Clearly, the skilled person would

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

not consider moving one of these elements to a release liner that is removed prior to use of the appliance.

Furthermore, Applicants do not agree with the Examiner's conclusion regarding the compactness of the Figure 3 embodiment of Sato. Respectfully, whether the embodiment of Sato Figure 3 is more compact than the embodiment of Sato Figure 5 is not relevant since in both embodiments the alignment elements 6 and 9 remain in place during use and create a certain thickness and stiffness that can cause discomfort to the user as the user moves and bends the stomal area. With the present invention, the alignment element on the release liner is removed before use, resulting in greater comfort for the user than is possible with any of the embodiments shown in Sato. Sato is simply not able to obtain the compact profile of the present invention, and the resulting comfort that this low profile provides.

Petersen discloses a release liner 54 having a hole 44 which the Examiner has interpreted as an alignment element. But Petersen does not disclose an alignment element on the outer receiving member that cooperates with an alignment element on the release liner such that the first flange is retained relative to the second flange in a direction parallel with the flanges, as provided in amended claim 1.

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

Finally, even if the skilled person were to combine Sato and Petersen, the result would not render the present invention obvious because the skilled person, in adding the release liner of Petersen to Sato, would apply the release liner to the adhesive 151. Hence, after removal of the release liner, the alignment elements 6 and 9 would still result in a "thick" appliance as measured in a direction parallel with a line passing through the flange 22, the flange 7, and the adhesive plate 1 of Sato. And neither Sato nor Petersen suggest or disclose a configuration in which the alignment element of Sato would be moved from the flanges to a release liner. Again, such a configuration would not work since Sato requires that the alignment elements be retained in use.

Applicants request reconsideration by the Examiner of her conclusion that the movement of the alignment element to the release liner as claimed by the present invention is simply a rearrangement involving only routine skill. On the contrary, the inclusion of a first alignment element on the release liner and a second alignment element on the outer receiving member flange that is adapted to cooperate with the first alignment element of the release liner such that the inner bag liner flange is retained in a direction substantially parallel with the outer

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

receiving member flange goes well beyond such routine skill and is not shown or suggested by the prior art.

In view of the foregoing amendments and remarks, claim 1 is patentable over the prior art. Claims 2, 3 and 5-24 are also allowable as claims properly dependent on an allowable base claim. Favorable reconsideration and allowance of the pending claims is requested.

New claim 32 represents the subject matter of claim 22 rewritten in independent form to include the limitations of previously pending claims 1 and 19. Claim 32 is presented as being in condition for allowance in accordance with the Examiner's indication of allowable subject matter in claim 22, the Examiner's statement of reasons for such indication, and the prior art. Favorable consideration and allowance of claim 32, as well as claims 33-35 dependent thereon, is requested.

With the foregoing amendments and remarks, the present application is in condition for allowance.

Serial No.: 10/591,450
Atty. Docket No.: P71418US0

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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